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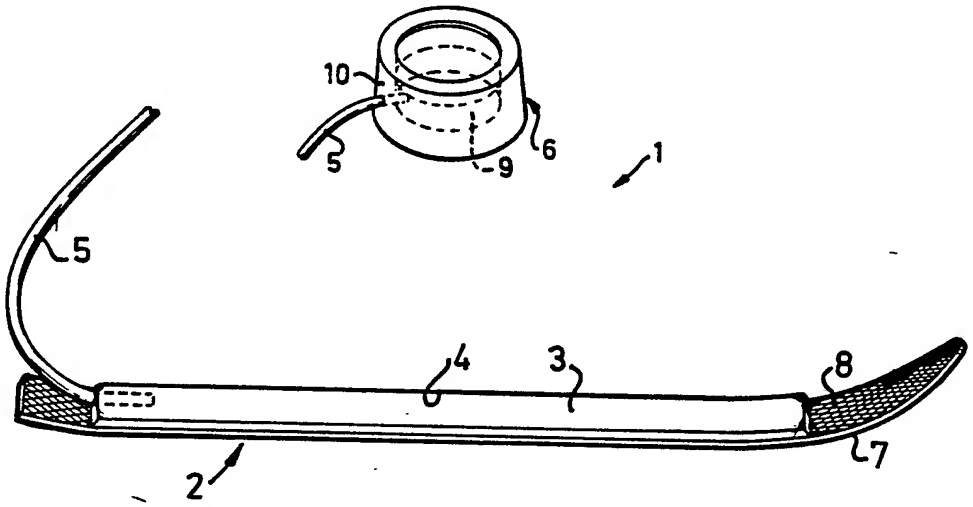
(54) Title: SURGICAL DEVICE



(57) Abstract

A device (1) for banding of the stomach (11) of a patient, such as a patient suffering from obesity, which device comprises a band (2) arranged to be joined into a ring around the stomach and provided with a lumen (3) filled with a fluid, in which lumen the amount of fluid can be changed via an injection port (6) placed under the skin of the patient, thus that the cross-sectional area of the ring can be varied.

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Surgical device

Technical field

The present invention is related to a surgical device for banding of the stomach of a patient who benefits from such banding, preferably for decreasing food intake. A method of banding the stomach of a patient and a method for treatment of obesity in a patient constitute further aspects of the invention.

An object of the invention is to achieve banding of the stomach that can be modified without a renewed surgical incision.

State of the art

A method in use at present for treatment of obese patients comprises applying a stricture on the stomach by means of a band or similar, which at a surgical incision is fixed to a certain predetermined circumference. However it has turned out that the stricture in many cases is either too big or too small. This has led to renewed incisions in nearly half of the cases.

Description of the invention

According to the present invention it is provided a surgical device for banding of the stomach of a patient, comprising a band arranged to be joined with itself to a ring around the stomach. The device is characterized in that the band has a lumen filled with fluid and having a flexible wall, which on application is oriented in towards the stomach, in which lumen the amount of fluid can be increased or decreased via a conduit for the fluid connected to the lumen and debouching in an injection port intended to be placed under the skin of the patient. With the device a decrease or increase of the free cross-sectional area defined by said ring is achieved.

With the device according to the invention the band can be placed around the stomach filled with a predetermined amount of fluid in the lumen which provides the intended stricture of the stomach. If later said stricture turns out to be too narrow or too wide, it can be widened or narrowed in a desired degree by insertion of a syringe needle through the skin of the patient into the injection port and withdrawal or injection of fluid.

According to a preferred embodiment of the invention the lumen extends along an intermediate portion of the band, whereby the band has free ends arranged to be joined to each other. The joining can preferably be done by overlapping the free band ends and suturing them together. For this purpose the band can have a reinforcement, for example a net reinforcement which prevents the suture from tearing up the band.

It is preferred to provide the band with a number of attachment ears for suturing the band to body tissues, preferably to the outer wall of the stomach.

The fluid in the device can be a gas but is preferably a liquid. In the choice of liquid it should be taken into account that it should not to a substantial degree be able to penetrate the wall material forming the lumen, the conduit and the injection port. Furthermore it should be taken into account that the liquid should be physiologically innocuous for the event that it still could leak out into the organism, for example due to damage to the device, inappropriate handling or defects in material. Osmolarly active or inactive liquids can be used. A preferred liquid is oil such as peanut oil, soy oil, another vegetabilic oil or paraffin oil. Other preferred liquids are water, dextrane solution or sodium chloride solution, preferably isotonic sodium chloride solution. The liquid can, in case of need, contain bacteriostatically acting compounds.

The injection port can be designed in a manner known per se, but consists preferably of a beaker-shaped body in the interior of which the conduit for the fluid debouches, which body is moulded into a soft material, penetrable by an injection needle.

The invention is further described with reference to the enclosed drawings wherein

Fig. 1 is an elevational view of a device according to the invention,

Fig. 2 is a view from a low angle of the band comprised in the device of Fig. 1; and

Fig. 3 is an overview which schematically shows a device according to the invention in position around the stomach.

According to the invention 1 denotes a band 2, which on one side has a lumen 3 filled with a liquid, said lumen having a flexible wall 4. The lumen is in liquid communication with a conduit 5 for the liquid which debouches in an injection port 6. The conduit can be cut by the surgeon and joined to a length suitable for the individual patient, and can for this purpose be provided with a connector pipe (not shown).

The band 2 comprises a support strap 7 of material of sufficient flexibility to be joined to a ring and not to cause trauma on parts of tissue brought in contact therewith. In the support strap a net reinforcement 8 is included. The lumen 3 consists according to figs. 1 and 2 of a section of tubing closed at its ends and glued to the support strap. Alternatively the support strap can constitute one of the walls of the lumen. The other wall 4 of the lumen is intended to be oriented in towards the stomach on application and is made up of soft flexible material to have the ability to expand on filling with liquid. Said wall 4 can optionally be made up of elastic material.

The injection port 5 contains a beaker-shaped body 9 suggested with interrupted lines in fig. 1 and moulded into a cover 10 of soft material.

In fig. 2 an arrow shows how liquid can be introduced via the conduit 5 for the fluid into the lumen which therein is shown in partially expanded condition.

In fig. 3 the stomach is denoted 11 and the band joined into a ring is denoted 12.

Preferably the length of the band can be between 60 and 200 mm, whereby the lumen occupies between 40 and 170 mm, and the width between 5 and 20 mm. The volume of liquid in the lumen in completely expanded condition can suitably be between 2 and 20 ml. By choosing said parameters, material and thickness of goods the free cross-sectional area defined by the band in ring-shape can be made to decrease by about 80% from a largest area which is between 150 and 2500 mm^2.

The material in the device should be physiologically innocuous and non-irritating to tissues in all parts thereof brought in contact with body tissues. The band, the walls of the lumen, the conduit and the outer part of the injection port can suitably be made up by silicon rubber while the beaker-shaped body of the injection port suitably can be made up by HD-polyethylene or polyamide.

Claims

1. A surgical device for banding of the stomach of a patient, comprising a band arranged to be joined with itself into a ring around the stomach, characterized in that the band has a lumen filled with fluid, said lumen having a flexible wall which on application is oriented in towards the stomach, in which lumen the amount of fluid can be increased or decreased via a conduit for the fluid connected to the lumen and debouching in an injection port intended to be placed under the skin of the patient, whereby is achieved an increase or a decrease respectively of the free cross-sectional area defined by said ring.

2. A device according to claim 1, characterized in that the lumen extends along an intermediate part of the band and the band has free ends arranged to be joined to each other.

3. A device according to claim 1 or 2, characterized in that the band has a number of attachment ears for suturing of the same to body tissues.

4. A device according to one or more of the preceding claims, characterized in that the fluid is a liquid.

5. A device according to claim 4, characterized in that the liquid is an oil.

6. A device according to claim 4, characterized in that the liquid is an isotonic sodium chloride solution.

7. A device according to one or more of the preceding claims, characterized in that the injection port consists of a beaker-shaped body in the interior of which a conduit for the fluid debouches, which body is moulded into a soft material penetrable for an injection needle.

8. A method of banding the stomach of a patient, characterized in that the stomach is banded with employment of a device according to one or more of the preceding claims.

9. A method of treatment of obesity in a patient, characterized in that the stomach of the patient is banded at a surgical incision using a device according to one or more of claims 1-6, whereupon in case of need the banding is modified by injection or withdrawal of fluid through the injection port.

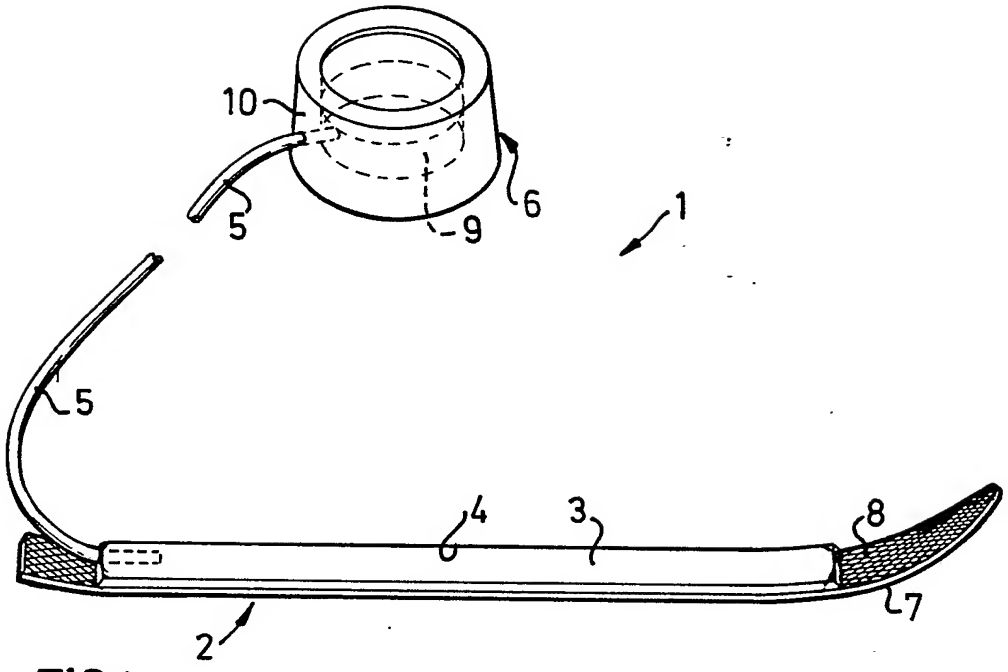

FIG.1

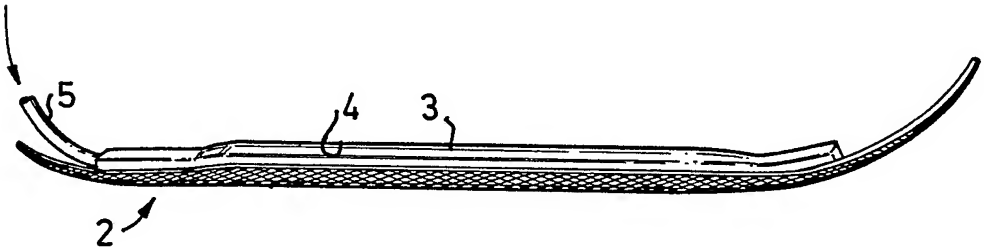

FIG. 2

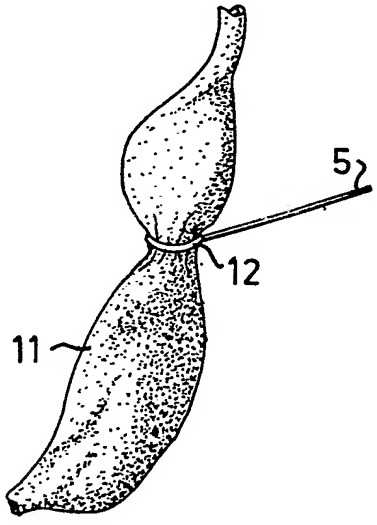

FIG. 3

INTERNATIONAL SEARCH REPORT

PCT/SE86/00037

International Application No

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [6]

According to International Patent Classification (IPC) or to both National Classification and IPC [4]

A 61 B 17/00

II. FIELDS SEARCHED

Minimum Documentation Searched [7]

Classification System	Classification Symbols
IPC 4	A 61 B 12/00, /12, 22, 19/00; A 61 F 2/02
US Cl	118:1, 328, 329, 346; 3:36

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [8]

SE, NO, DK, FI classes as above

III. DOCUMENTS CONSIDERED TO BE RELEVANT [9]

Category [10]	Citation of Document, [11] with indication, where appropriate, of the relevant passages [12]	Relevant to Claim No. [13]
A	US, A, 4 399 809 (BARO ET AL) 23 August 1983 col 1, line 33-35	1-7
A	US, A, 4 246 893 (BERSON) 27 January 1981	1-7
A	Läkartidningen 13/83, March 83, J M Solhaug "Gastric Banding - En ny metod vid behandling av adipositas, p 1327-1328	1-7

* Special categories of cited documents: [10]

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

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"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
1986-03-10	1986-03-26
International Searching Authority	**Signature of Authorized Officer**
Swedish Patent Office	Christer Wendenius

MJ

Form PCT/ISA/210 (second sheet) (January 1985)

FURTHER INFORMATION CONTINUED FROM THE SECOND SHEET

V. [X] OBSERVATIONS WHERE CERTAIN CLAIMS WERE FOUND UNSEARCHABLE [1]

This international search report has not been established in respect of certain claims under Article 17(2) (a) for the following reasons:

1. [X] Claim numbers 8, 9, because they relate to subject matter not required to be searched by this Authority, namely:

Methods for treatment of the human body by surgery or therapy.

2. [ ] Claim numbers....., because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claim numbers....., because they are dependent claims and are not drafted in accordance with the second and third sentences of PCT Rule 6.4(a).

VI. [ ] OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING [2]

This International Searching Authority found multiple inventions in this international application as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims of the international application.
2. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims of the international application for which fees were paid, specifically claims:
3. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claim numbers:
4. [ ] As all searchable claims could be searched without effort justifying an additional fee, the International Searching Authority did not invite payment of any additional fee.

Remark on Protest

- [ ] The additional search fees were accompanied by applicant's protest.
- [ ] No protest accompanied the payment of additional search fees.

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TITLE: SURGICAL DEVICE

PUBN-DATE: August 14, 1986

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INT-CL (IPC): A61B017/00

EUR-CL (EPC): A61B017/12 , A61F005/00

ABSTRACT:

CHG DATE=19990617 STATUS=O>A device (1) for banding of the stomach (11) of a patient, such as a patient suffering from obesity, which device comprises a band (2) arranged to be joined into a ring around the stomach and provided with a lumen

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